20. (Amended) A device for enhancing solution vapor sterilization of the lumen of a medical instrument, said device comprising a vessel for containing an antimicrobial solution, and means for connecting said vessel to the end of said lumen to provide antimicrobial vapor directly to the lumen during the solution vapor sterilization said device being sealed from the ambient atmosphere except through said means for connecting.

REMARKS

The present Amendment is being filed under certificate of mailing as indicated and appropriate Petition For Extension of Time requesting an extension of time of three (3) months to respond to the outstanding Office Action is accompanying this Amendment and also filed under certificate of mailing.

Essentially the claims of the present application have been rejected under 35 USC 102 as being anticipated by the Spanel and Wyka references. Spanel describes a means for treating articles such as bedding or blankets in order to disinfect or deodorize or fumigate the fabric. The device has a means for air entering one end through a holder holding volatile liquids, chemicals or compositions and that air is further drawn into the device in order to treat the fabrics. Referring to the figures, a body 10 of rubberized fabric is shown with a band of porous fabric indicated as 15 at one end and an attachment for a vacuum means at the other end. Clearly, the Spanel reference describes a flow-through type device where external air is passed through the body 10 and out the opening formed by the tubing 14.

The Wyka reference has an opening to which flexible conduit 6 is attached and exits to which conduits 10 and 12 are connected to through which air or other gas flows.

Thus, it is easily seen that the two references cited in the present application both maintain a flow-through type operation.

That is, one end is openly communicating with the ambient atmosphere through which a gas, most likely air, is drawn into the device and exits through another opening. Applicants assume that the Examiner is citing these entire devices against the claims of the present application. Claim 11 has been amended in order to describe that the device is sealed off against the ambient atmosphere but for the opening which is attached to the lumen. Thus, the present device is not anticipated by either of the two references, made obvious by the two references, nor operates in the same manner as those cited in the references. The present device is filled with an antimicrobial fluid normally, such as for example a hydrogen peroxide solution. The device is attached to a lumen which is then disposed in a sterilization chamber. In use the sterilization chamber is evacuated and this reduction in the ambient pressure causes the hydrogen peroxide solution in the device to vaporize and pass through the lumen just as if it were being sucked out through a straw. This assures exposure of the internal surface of the lumen to the antimicrobial solution.

Devices of the type cited against the present apparatus, however, if used in such an environment, would merely have a backflow. That is, the rear openings of the devices having no lumen attached thereto would present less resistance to the ambient vacuum and, therefore, the hydrogen peroxide, once vaporized, would be evacuated through the rear end of the apparatus and not through the lumen as is required for appropriate sterilization. Furthermore, each of the devices requires a mechanical addition of force or momentum to the gas in order to force it to pass through the device. That is, some sort of fan or vacuum must be placed to the device directly in order to pull the air through the device in order to circulate it as shown in these references. The present device, however, no additional mechanical means are necessary as the ambient vacuum inherently pulls the vaporized antimicrobial

solution through the lumen in response to the vaporization of the antimicrobial solution in the device caused by the reduction in pressure. Therefore, the differences between the claimed invention and those cited in the references contained in the Office Action are significantly difference and not merely one of form.

Claim 12 additionally describes the means for attachment of the device to the lumen. The device is described as having one end which is securely attached about the opening of the vessel and the other end which is an elastic ring for releasable attachment to the end of the article. This provides a sealing-type attachment means which permits the function described above in an apparatus using a reduction in pressure as part of the sterilization cycle. Such a sealing attachment is unnecessary in the references cited in the Office Action as both devices provide for a flow through of the gas through the device.

Claim 13 further describes the structure of the attachment device of Claim 12 and should be allowable with Claim 12 and Claim 11.

Claim 14 describes a further attachment means which comprises a flexible bushing disposed within the opening of the vessel for receiving one end of the article. Neither of the references cited by the Examiner describes such a flexible bushing which receives one end of an article. Therefore, Claim 14 is fully allowable over the references cited in the Office Action.

Claim 15 further describes the structure of Claim 14 and is allowable for the reasons mentioned above in connection with Claim 14 and is further allowable as being depending ultimately on Claim 11.

Claim 16 calls for the vessel to comprise a flexible pouch and the means for connecting the vessel to the end of the lumen comprising a drawstring. This claim is ultimately dependent on Claim 11 and should be allowable therewith. Clearly, the flexible

pouch is sealed against the ambient atmosphere except through the opening described in that claim. This is distinguished from the references cited for the reasons described above.

Claim 17 calls for a second opening in the vessel for containing a measured aliquot of antimicrobial solution. Again, although there is a second opening in the vessel, this vessel is actually sealed by the cartridge containing the measured aliquot of antimicrobial solution. Therefore, there is still no flow through of the ambient air through the device. For these reasons and the reasons described above, this claim is fully allowable over the references cited.

Claim 18 calls for the device wherein the vessel contains a porous absorbent substrate which contains the antimicrobial solution. Again, this is ultimately dependent on Claim 11 and should be allowable therewith.

Claim 19 calls for the device wherein the vessel has means for attaching a removable closure cap to the opening thereof. This clearly indicates a device wherein the antimicrobial solution is protected by the closure cap. This claim is, therefore, fully allowable.

Claim 20 has been similarly amended in order to contain the limitation that the device is sealed from the ambient atmosphere except through said means for connecting. Thus, the arguments presented above in connection with Claim 11 apply equally well to Claim 20 and Claim 20 is fully allowable over the references cited.

Claim 21 depends on Claim 20 and calls for the means for connecting the vessel to the end of the lumen to comprise an expandable sheath having one end securely attached about the opening of the vessel and the other end comprising an elastic ring for releasable attachment about the end of the instrument, including the lumen. Thus, it is seen that for the reasons described above in connection with Claims 12 and 13, Claim 21 is

fully allowable over the references cited in the present Official Action.

Claim 22 depends on Claim 21 and includes the limitation that the sheath is firmly attached to the vessel by means of a second elastic ring. This claim is fully allowable as dependent ultimately on Claim 20 and directly on Claim 21.

For the reasons described above, Applicants respectfully submit that the claims of the present application as now presented are fully allowable over the references cited by the Examiner in the outstanding Office Action. Reconsideration and early notice of allowance are respectfully requested.

Respectfully submitted,

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